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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,516	04/14/1999	JANAKIRAMAN RAMACHANDRAN	1103326-0557	2416
7470	7590	03/08/2004	EXAMINER	
WHITE & CASE LLP PATENT DEPARTMENT 1155 AVENUE OF THE AMERICAS NEW YORK, NY 10036			SEAMAN, D MARGARET M	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/284,516

Applicant(s)

RAMACHANDRAN, JANAKIRAMAN

Examiner

D. Margaret Seaman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

This application was filed 4/14/1999 and is a 371 of PCT/SE99/00319 (filed 3/4/1999) which claims priority to India 464/MAS/98 (3/6/1998) and Sweden 9801370-9 (4/20/1998). The office action of 2/10/2000 has been withdrawn as not being timely. Claims 1-11 are before the Examiner.

#### *Claim Rejections - 35 USC § 101*

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-7 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter, i.e. "Use of" is not a statutory subject matter; however, "A method of using..." is proper statutory subject matter. Claims 1-7 are withdrawn from further consideration as being drawn to non-statutory subject matter.

#### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims are ambiguous as

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being dependent from a claim that is drawn to non-statutory subject matter. Correction is required.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of mycobacterium tuberculosis, does not reasonably provide enablement for the treatment of any and all diseases caused by mycobacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. All of the tests within the specification are drawn to the treatment of mycobacterium tuberculosis. The specification does not test nor does it provide a nexus between M.bovis, M. avium or M. marimum and mycobacterium tuberculosis.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/29272 and WO 93/12085.

WO 94 teaches in a small Markush the compounds of claim 8 (see page 2 line 10-30 and page 9 line 25+). The process of claim 9 is disclosed within a small Markush on page 7 lines 1-20). The pharmaceutical composition of claim 10 is disclosed on page 13.

WO 93 teaches claim 8 on page 3. Claim 9 is taught on pages 8-9. The composition of claim 10 is taught on page 17.


The difference between the prior art and the instantly claimed compounds is that the prior art (WO94 and WO 93) is that the prior art teaches a small Markush of compounds but does not specifically have an example wherein the X moiety (of the prior art) is an unsubstituted phenyl and is in the position required by the instant claims.

However, it would have been obvious to one of ordinary skill in the art that the instantly claimed compounds could be made by the same process taught by the WOs with the result of getting compounds of the scope of the instant claims while having pharmaceutical activity. Rationale: The WOs teaches a large Markush and several smaller markushes. The smaller markushes contain the instantly claimed (claim 8) scope. The process for making the compounds (claim 9) does not differ with the exception of the specific X substituent from the instant claims. The different X moiety would not be expected to interfere with the process taught by the WOs with the small change of the X to phenyl. The WOs teach a small Markush with the expectation that any compound that fits within that Markush would have pharmaceutical activity. Therefore the instantly claimed pharmaceutical composition (claim 10) would be encompassed by the teachings of the composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 571-272-0694. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
D. Margaret Seaman  
Primary Examiner  
Art Unit 1625

dms